

Southern Derbyshire District Prescribing Advisory Group

Guideline for assessing evidence on effectiveness of new drugs

What is the aim of this guideline?

This guideline outlines the procedure for preparing evaluations of new drugs for the District Prescribing Advisory Group. This will ensure that bias, misunderstandings and omissions are minimised when assessing research findings. In addition, this guideline will ensure that findings will be communicated to the group effectively and succinctly.

How are evaluations requested?

Evaluations may be requested by:

- An individual consultant, GP or other health professional
- If the drug has been previously approved by another Drug and Therapeutics Committee, e.g. Acute Trust, Mental Health
- Via a PCG prescribing adviser/prescribing lead
- Via the Health Authority

What is the standard format for the evaluations?

A standard format ensures that all relevant points are covered:

- **Introduction:** this provides information on, e.g. mechanism of action, doses etc.
- **Clinical evidence:** this section summarises the major trials involving the drug. This should include trial methodology, participants (e.g. numbers completing, lost to follow up), comparison groups, outcomes and any comments.
- **Adverse effects**
- **Cautions/contra-indications/interactions:** if appropriate
- **Place in therapy:** recommendations should be based on facts, not preferences
- **Issues for discussion** at the Prescribing Advisory Group
- **Cost implications**

- **References:** cited as in Index Medicus

Reviews are generally around two pages long and should be dated. Recommendations can be reviewed if significant evidence is subsequently published.

What search strategies should be used?

Various sources of evidence-based information should be used (see Appendix 1). A record should be kept of the sources and keywords used in the search.

What are the criteria for the inclusion of studies in evaluations?

The best available **published** evidence should be used. Randomised controlled trials and systematic reviews are generally considered to be gold standard evidence. Abstracts and conference reports are not usually of sufficient quality to be considered.

Reviews by other organisations, e.g. National Prescribing Centre, MTRAC etc. may help avoid duplication of effort locally. However, if a new drug review is somewhat out of date, the review should either be updated or a new review prepared.

How should the methodological quality of the trials be assessed?

Evidence should be classified according to the following scheme:

Evidence level

- Ia** Evidence obtained from meta-analysis of RCTs*
- Ib** Evidence obtained from at least one RCT
- IIa** Evidence obtained from at least one well designed controlled study without randomisation
- IIb** Evidence obtained from at least one other type of well-designed quasi-experimental study
- III** Evidence obtained from well-designed non-experimental descriptive studies, e.g. case series, cross sectional studies.
- IV** Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

* One good quality large RCT may be better quality evidence than, e.g. a meta-analysis of small, or observational, studies.

Grade of recommendation

- A requires at least one RCT as part of a body of literature of overall good quality and consistency. (Evidence levels Ia, Ib)
- B requires the availability of well conducted clinical studies but no RCTs. (Evidence levels IIa, IIb, III)
- C requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

These grades originate from US agency for Health care policy and research.

How should costs be addressed?

Direct NHS costs of prescribing should be estimated for a specified length of time, e.g. 28 days. Costs should be compared with other similar drugs. If possible, an estimate of the cost of use in SDHA should be made using information from PACT data.

Use most recent MIMS/Drug Tariff.

Appendix 1

Search strategy for answering drug information enquiries

- Not all sources need always be used.
- These are just a selection of main internet and journal sources.

General sources

- BNF
- SPC/electronic medicines compendium
- Martindale
- In-house filing system
- New drugs file (includes NPC evaluations, trent new product evaluations etc.)
- Electronic BNF/Drug and Therapeutics Bulletin/MeReC Bulletin
- Clinical Evidence
- Combined table of contents (published by NPC)
- Current Problems in Pharmacovigilance

Databases

- OVID
- Pharmline
- Cochrane Library
- Medline
- Medscape
- SUMsearch (incorporates DARE/HTA/Medline/Merck Manual/National Guidelines)

Internet sources

Journals

Evidence-based medicine sources

- Aggressive Research Intelligence facility (ARIF)
- Centre for Evidence Based Medicine
- Health Technology Assessment (HTA)
- Midlands Therapeutic Review & Advisory Committee (MTRAC)
- National Electronic Library for Primary Care
- NHS Centre for Reviews and Dissemination
- North of England guidelines
- SchARR
- SHPIC
- Scottish Intercollegiate Guidelines Network (SIGN)
- Trent Institute Working Group on Acute Purchasing
- Turning Research into Practice (TRIP) database

- Wessex Development and Evaluation Committee

Pharmaceutical company medical information departments